



10/544,259
USPTO Rec'd PCT/PTO 07 APR 2006

PCT

Atty. Dkt. No. MARKS0801
(041376-0801)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alterschopfer and Watkinson

Title: TRANSDERMAL
GRANISETRON

Appl. No.: 10/544,259

Filing Date: 08/03/2005

Examiner: Not yet assigned

Art Unit: 1732

Conf. No. 1348

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

Stephen E. Reiter

(Printed Name)

(Signature)

4/4/06

(Date of Deposit)

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment-IDS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

Atty. Dkt. No. MARKS0801
(041376-0801)

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language documents is described in the present specification. An English translation of the foreign-language documents is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

Respectfully submitted,

Date 4/4/06

By Stephen E. Reiter

FOLEY & LARDNER LLP
Customer Number: 30542
Telephone: (858) 847-6711
Facsimile: (858) 792-6773

Stephen E. Reiter
Attorney for Applicant
Registration No. 31,192

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APR 07 2006

Use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

Application Number	10/544,259
Filing Date	August 3, 2005
First Named Inventor	Peter Altenschopfer
Group Art Unit	
Examiner Name	

Attorney Docket Number

MARKS0801 (041376-0801)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

U.S. PATENT APPLICATION DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Application Document		Name of Patentee or Applicant of Cited Document	Filing Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A1	WO	94/07468		Cygnus Therapeutic Systems	04-14-1994		
	A2	WO	98/53815		Minnesota Mining and Manufacturing Company	12-03-1998		
	A3	WO	00/47208		Samyang Corporation	08-17-2000		
	A4	WO	01/74338		LTS Lohmann Therapie-Systeme AG	10-11-2001		
	A5	WO	04/069141 A2		Strakan Limited	08-19-2004		
	A6	EP	1064939 A		Novosis Pharma AG	06-26-2000		
	A7	JP	8-34731			02-06-1996		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A8	Biswas and Rudra, Comparison of granisetron and granisetron plus dexamethasone for the prevention of postoperative nausea and vomiting after laparoscopic cholecystectomy. Acta Anaesthesiol Scand., 47:79-83, 2003.	

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of 2

Complete if Known

Application Number	10/544,259
Filing Date	August 3, 2005
First Named Inventor	Peter Altenschopfer
Group Art Unit	
Examiner Name	
Attorney Docket Number	MARKS0801 (041376-0801)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A9	Cupissol et al., Evaluation of the bioequivalence of tablet and capsule formulations of granisetron in patients undergoing cytotoxic chemotherapy for a malignant disease. J.Pharm.Sci., 82:1281-1284, 1993.	
	A10	Friedman et al., Oral granisetron for the prevention of acute late onset nausea and vomiting in patients treated with moderately emetogenic chemotherapy. Oncologist, 5:136-143, 2000.	
	A11	Gralla et al., Recommendations for the use of antiemetics: Evidence based, clinical practice guidelines. Journal of Clinical Oncology, 17:2971-2994, 1999.	
	A12	Guillem et al., High efficacy of oral granisetron in the total control of cyclophosphamide-induced prolonged emesis. Proceedings of the American Society of Oncology, 17:46, 1998.	
	A13	Kalaycio et al., Continuous-infusion granisetron compared to ondansetron for the prevention of nausea and vomiting after high-dose chemotherapy. J. Cancer Res. Clin. Oncol., 124:265-269, 1998.	
	A14	Noble et al., A double-blind, randomized, crossover comparison of granisetron and ondansetron in 5-day fractionated chemotherapy: assessment of efficacy, safety and patient preference. Eur. J. of Cancer, 30: 1083-1088, 1994.	
	A15	Physicians Desk Reference (2001) entry for Kytril®	
	A16	Porzio et al., Pruritus in a patient with advanced cancer successfully treated with continuous infusion of granisetron. Support Care Cancer, January 21, 2004.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.